

Version: May2011
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL
Vehicle: FEED

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Study Summary

| Laboratory Name | Study Number | Study Start Date | Length of Study in Days | Number of Animals Total and (#/Cage) | Number Surviving and (Mean Life Span) | Maximum Mean Weekly Body Weight | Chemical |
|------------------------------|--------------|------------------|-------------------------|--------------------------------------|---------------------------------------|---------------------------------|------------------------------|
| Male | | | | | | | |
| Battelle Columbus Laboratory | 059901305 | 05/12/05 | 726 | 50(3) | 36(685) | 522.7 | Styrene-acrylonitrile trimer |
| Female | | | | | | | |
| Battelle Columbus Laboratory | 059901305 | 05/13/05 | 727 | 50(5) | 41(699) | 371.2 | Styrene-acrylonitrile trimer |

NOTE: The text on page 2 ("Report Description") describes how the studies listed here are displayed on the data pages that follow.

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| | | Male | | | Female | | |
|--------------------------------------|-------|-------------|----------|-------|-------------|-------------|----------------|
| #All Organs: | | | | | | | |
| Benign Tumors | | | | | | | |
| | | 46/50 (92%) | | | 42/50 (84%) | | |
| Overall Incidence | Total | 46/50 (92%) | Mean 92% | SD 0% | Total | 42/50 (84%) | Mean 84% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant Tumors | | | | | | | |
| | | 22/50 (44%) | | | 19/50 (38%) | | |
| Overall Incidence | Total | 22/50 (44%) | Mean 44% | SD 0% | Total | 19/50 (38%) | Mean 38% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant and Benign Tumors | | | | | | | |
| | | 49/50 (98%) | | | 44/50 (88%) | | |
| Overall Incidence | Total | 49/50 (98%) | Mean 98% | SD 0% | Total | 44/50 (88%) | Mean 88% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangioma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangiosarcoma or Hemangioma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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| | Male | | | | Female | | | |
|--|-------|-------------|----------|-------|-------------|-------------|----------|-------|
| #All Organs: | | | | | | | | |
| Histiocytic Sarcoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Leukemia: Erythrocytic | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated | | | | | | | | |
| | | 15/50 (30%) | | | 13/50 (26%) | | | |
| Overall Incidence | Total | 15/50 (30%) | Mean 30% | SD 0% | Total | 13/50 (26%) | Mean 26% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Mesothelioma: Benign | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Mesothelioma: Benign, Malignant, NOS | | | | | | | | |
| | | 4/50 (8%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 4/50 (8%) | Mean 8% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |

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| | | Male | | | Female | | |
|--------------------------------|-------|------|------|---------|--------|-------|-----------|
| #All Organs: | | | | | | | |
| Mesothelioma: Malignant | | | | | | | |
| | | 4/50 | (8%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 4/50 | (8%) | Mean 8% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Osteoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Osteosarcoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Adrenal Cortex: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 | (0%) | | 1/50 | (2%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) |
| | | | | | | | Mean 2% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Adrenal Cortex: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |

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#: Denominator is number of animals necropsied

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| | | Male | | | | Female | | | |
|--|-------|------|------|---------|-------|--------|------|------|---------------|
| *Adrenal Medulla: Ganglioneuroma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Adrenal Medulla: Hemangioma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Adrenal Medulla: Pheochromocytoma Benign | | | | | | | | | |
| | | 4/50 | (8%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 4/50 | (8%) | Mean 8% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Adrenal Medulla: Pheochromocytoma Complex | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Adrenal Medulla: Pheochromocytoma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| *Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS | | | | | | | | | |
| | | 4/50 | (8%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 4/50 | (8%) | Mean 8% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |

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#: Denominator is number of animals necropsied

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| | Male | | | | Female | | | |
|--------------------------------|-------|------|------|---------|--------|-------|------|------|
| #Bone: | | | | | | | | |
| Chordoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Bone: | | | | | | | | |
| Osteoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Bone: | | | | | | | | |
| Osteosarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Bone: | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| *Brain: | | | | | | | | |
| Astrocytoma Malignant | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| *Brain: | | | | | | | | |
| Ependymoma Benign | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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| | | Male | | | | Female | | | |
|-----------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| *Brain: | | | | | | | | | |
| Ependymoma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Glioma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Glioma Benign | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Glioma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Oligodendroglioma Benign | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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| | Male | | | | Female | | | |
|--|-------|------|------|---------|--------|-------|------|------|
| *Brain: | | | | | | | | |
| Oligodendroglioma Malignant | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| *Brain: | | | | | | | | |
| Oligodendroglioma, Glioma, or Astrocytoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| *Brain: | | | | | | | | |
| Osteosarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| *Brain: | | | | | | | | |
| Schwannoma Malignant | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| *Clitoral/Preputial Gland: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 1/50 | (2%) | | | 3/50 | (6%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 3/50 | (6%) |
| | | | | | | | | |
| *Clitoral/Preputial Gland: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |

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#: Denominator is number of animals necropsied

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| | Male | | | | Female | | | |
|--|-------|-----------|---------|-------|--------|-----------|---------|-------|
| *Clitoral/Preputial Gland: Carcinoma or Adenoma | | | | | | | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 3/50 (6%) | Mean 6% | SD 0% |
| | | | | | | | | |
| *Clitoral/Preputial Gland: Sarcoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Ear: Neural Crest Tumor | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Esophagus: Lipoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Eye: Melanoma Benign | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Eye: Melanoma Malignant | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |

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| | | Male | | | | Female | | | |
|-----------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #Eye: | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Harderian Gland: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Harderian Gland: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Harderian Gland: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Heart: | | | | | | | | | |
| Schwannoma Benign | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Heart: | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |

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| | Male | | | | Female | | | |
|---|-------|-----------|---------|-------|--------|-----------|---------|-------|
| #Intestine Large: Colon/Rectum: Adenoma | | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Intestine Large: Colon/Rectum: Carcinoma or Adenoma | | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Intestine Large: Colon/Rectum: Hemangioma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Intestine Small: Duodenum: Carcinoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Intestine Small: Duodenum: Leiomyoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Intestine Small: Duodenum: Schwannoma Malignant | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |

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 Tumor Incidence for Selected Control Animal Groups
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 Vehicle: FEED

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| | | Male | | | | Female | | | |
|--|-------|------|------|---------|-------|--------|------|------|---------------|
| #Intestine Small: Ileum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | |
| Granular Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | |
| Leiomyoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
 Vehicle: FEED

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| | | Male | | | Female | | |
|--|-------|-----------|---------|-------|--------|-----------|---------------|
| #Intestine Small: Site Unspecified: Carcinoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: Carcinoma or Adenoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: Granular Cell Tumor Malignant | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: Leiomyoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: Leiomyosarcoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: Schwannoma Malignant | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
 Vehicle: FEED

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 Report Date: 05/18/2011

| | | Male | | | | Female | | | |
|---|-------|------|------|---------|-------|--------|------|------|---------------|
| *Islets, Pancreatic: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| *Islets, Pancreatic: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Islets, Pancreatic: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | | | |
| Papilloma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
 Vehicle: FEED

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| | | Male | | | | Female | | | |
|--|-------|------|------|---------|-------|--------|------|------|---------------|
| *Kidney: Renal Tubule: Adenoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: Carcinoma or Adenoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: Lipoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: Mesenchymal Tumor Benign | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
 Vehicle: FEED

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| | | Male | | | | Female | | | |
|------------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| *Kidney: Renal Tubule: | | | | | | | | | |
| Mesenchymal Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Nephroblastoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Cholangioma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
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| | | Male | | | Female | | |
|--|-------|------|------|---------|--------|-------|-----------|
| *Liver: | | | | | | | |
| Hepatocellular Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Liver: | | | | | | | |
| Hepatocellular Carcinoma or Hepatoblastoma | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Liver: | | | | | | | |
| Hepatocellular Carcinoma or Hepatocellular Adenoma | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Liver: | | | | | | | |
| Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Liver: | | | | | | | |
| Ito Cell Tumor Benign | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Lung: | | | | | | | |
| Alveolar/Bronchiolar Adenoma | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
 Vehicle: FEED

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 Report Date: 05/18/2011

| | | Male | | | Female | | |
|---|-------|------|------|---------|--------|-------|-----------|
| *Lung: | | | | | | | |
| Alveolar/Bronchiolar Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Lung: | | | | | | | |
| Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma | | | | | | | |
| | | 1/50 | (2%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Lung: | | | | | | | |
| Fibrosarcoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Lung: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Lung: | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Lymph Node: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
 Vehicle: FEED

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| | Male | | | | Female | | | |
|---|-------|-----------|---------|-------|--------|-------------|----------|-------|
| #Mammary Gland: Adenolipoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Mammary Gland: Adenoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Mammary Gland: Carcinoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/50 (4%) | Mean 4% | SD 0% |
| | | | | | | | | |
| #Mammary Gland: Carcinoma or Adenoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/50 (4%) | Mean 4% | SD 0% |
| | | | | | | | | |
| #Mammary Gland: Fibroadenoma | | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 36/50 (72%) | Mean 72% | SD 0% |
| | | | | | | | | |
| #Mammary Gland: Fibroma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
 Vehicle: FEED

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| | | Male | | | Female | | |
|---|-------|------|------|---------|--------|----------|-------------|
| #Mammary Gland: | | | | | | | |
| Fibroma, Fibroadenoma or Adenoma | | | | | | | |
| | | 1/50 | (2%) | | 36/50 | (72%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 36/50 (72%) |
| | | | | | | Mean 72% | SD 0% |
| | | | | | | | |
| #Mammary Gland: | | | | | | | |
| Fibroma, Fibroadenoma, Carcinoma, or Adenoma | | | | | | | |
| | | 1/50 | (2%) | | 36/50 | (72%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 36/50 (72%) |
| | | | | | | Mean 72% | SD 0% |
| | | | | | | | |
| #Mesentery: | | | | | | | |
| Fibrous Histiocytoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | Mean 0% | SD 0% |
| | | | | | | | |
| #Mesentery: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | Mean 0% | SD 0% |
| | | | | | | | |
| #Mesentery: | | | | | | | |
| Lipoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | Mean 0% | SD 0% |
| | | | | | | | |
| #Mesentery: | | | | | | | |
| Schwannoma Malignant | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
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 Route: PERINATAL AND POSTNATAL
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| | | Male | | | Female | | |
|---|-------|-----------|---------|-------|-----------|-----------|---------------|
| *Nose: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Nose: | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | |
| Papilloma Squamous or Papilloma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | |
| Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | | | | |
| #Oral Mucosa: | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
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 Tumor Incidence for Selected Control Animal Groups
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 Vehicle: FEED

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| | Male | | | | Female | | | |
|---|-------|------|------|---------|--------|-------|------|------|
| #Oral Mucosa: | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Cystadenoma | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | | Total | 0/50 | (0%) |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Fibrosarcoma | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | | Total | 0/50 | (0%) |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Granulosa Cell Tumor Benign | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | | Total | 0/50 | (0%) |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Granulosa Cell Tumor Malignant | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | | Total | 0/50 | (0%) |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Granulosa Cell Tumor: Benign, Malignant, NOS | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | | Total | 0/50 | (0%) |
| | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
 Vehicle: FEED

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| Male | | | | Female | | | |
|--|-------|-----------|---------|--------|-----------|-----------|---------|
| *Ovary: | | | | | | | |
| Granulosa-Theca Tumor Benign | | | | | | | |
| | | | | 0/50 | (0%) | | |
| Overall Incidence | | | | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| *Ovary: | | | | | | | |
| Granulosa-Theca Tumor Malignant | | | | | | | |
| | | | | 0/50 | (0%) | | |
| Overall Incidence | | | | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| *Ovary: | | | | | | | |
| Schwannoma Malignant | | | | | | | |
| | | | | 0/50 | (0%) | | |
| Overall Incidence | | | | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| *Ovary: | | | | | | | |
| Tubulostromal Adenoma | | | | | | | |
| | | | | 0/50 | (0%) | | |
| Overall Incidence | | | | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| *Pancreas: | | | | | | | |
| Adenoma | | | | | | | |
| | | 1/50 | (2%) | | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 1/50 (2%) | Mean 2% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Pancreas: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
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| | | Male | | | Female | | |
|---|-------|-------|-------|----------|--------|----------|-------------|
| *Pancreas: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 1/50 | (2%) | | 1/50 | (2%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 1/50 (2%) |
| | | | | | | Mean 2% | SD 0% |
| | | | | | | | |
| *Pancreas: | | | | | | | |
| Mixed Tumor Benign | | | | | | | |
| | | 1/50 | (2%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) |
| | | | | | | Mean 0% | SD 0% |
| | | | | | | | |
| *Pancreas: | | | | | | | |
| Mixed Tumor Malignant | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | Mean 0% | SD 0% |
| | | | | | | | |
| *Parathyroid Gland: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/35 | (0%) | | 0/48 | (0%) | |
| Overall Incidence | Total | 0/35 | (0%) | Mean 0% | SD 0% | Total | 0/48 (0%) |
| | | | | | | Mean 0% | SD 0% |
| | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | |
| Adenoma | | | | | | | |
| | | 16/50 | (32%) | | 22/50 | (44%) | |
| Overall Incidence | Total | 16/50 | (32%) | Mean 32% | SD 0% | Total | 22/50 (44%) |
| | | | | | | Mean 44% | SD 0% |
| | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | Mean 0% | SD 0% |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
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 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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| | | Male | | | Female | | |
|---|-------|-------------|----------|-------|-------------|-------------|----------------|
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 16/50 (32%) | | | 22/50 (44%) | | |
| Overall Incidence | Total | 16/50 (32%) | Mean 32% | SD 0% | Total | 22/50 (44%) | Mean 44% SD 0% |
| | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | |
| Ganglioneuroma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Pituitary Gland: Pars Nervosa: | | | | | | | |
| Craniopharyngioma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Prostate: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 (0%) | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | | | |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
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| | | Male | | | | Female | | | |
|-------------------------------|-------|------|------|------|---------|--------|-------|---------|-------|
| *Prostate: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | | 0/50 | (0%) | | | | | |
| Overall Incidence | Total | | 0/50 | (0%) | Mean 0% | SD 0% | | | |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | |
| | | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Seminal Vesicle: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | | 0/50 | (0%) | | | | | |
| Overall Incidence | Total | | 0/50 | (0%) | Mean 0% | SD 0% | | | |
| | | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
 Vehicle: FEED

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 Report Date: 05/18/2011

| | | Male | | | | Female | | | |
|--|-------|------|------|---------|-------|--------|------|------|---------------|
| #Skeletal Muscle: | | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Rhabdomyosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Rhabdomyosarcoma or Rhabdomyoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Adenoma or Basosquamous Tumor Benign | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
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| | Male | | | | Female | | | |
|---|-------|------|-------|----------|--------|-------|------|---------|
| #Skin: | | | | | | | | |
| Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Basal Cell Carcinoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma | | | | | | | | |
| | | 4/50 | (8%) | | | 1/50 | (2%) | |
| Overall Incidence | Total | 4/50 | (8%) | Mean 8% | SD 0% | Total | 1/50 | (2%) |
| | | | | | | | | Mean 2% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibroma | | | | | | | | |
| | | 5/50 | (10%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 5/50 | (10%) | Mean 10% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
 Vehicle: FEED

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| | Male | | | | Female | | | |
|--|-------|------------|----------|-------|--------|-----------|---------|-------|
| #Skin: | | | | | | | | |
| Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | |
| | | 5/50 (10%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 5/50 (10%) | Mean 10% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibrosarcoma | | | | | | | | |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
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| | Male | | | | Female | | | |
|--|-------|------|------|---------|--------|-------|------|---------|
| #Skin: | | | | | | | | |
| Keratoacanthoma | | | | | | | | |
| | | 2/50 | (4%) | | | 1/50 | (2%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 1/50 | (2%) |
| | | | | | | | | Mean 2% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Lipoma | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Liposarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Neural Crest Tumor | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Neural Crest Tumor, Malignant | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Neurofibroma or Schwannoma benign | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
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| | Male | | | | Female | | | |
|--|-------|-----------|---------|-------|-----------|-----------|---------|-------|
| #Skin: | | | | | | | | |
| Neurofibrosarcoma or Schwannoma (malignant or NOS) | | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) | | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Sarcoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Schwannoma Benign | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Schwannoma Malignant | | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
 Vehicle: FEED

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 Report Date: 05/18/2011

| | Male | | | | Female | | | |
|---|-------|-----------|---------|-------|--------|-----------|---------|-------|
| #Skin: | | | | | | | | |
| Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma or Papilloma | | | | | | | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma | | | | | | | | |
| Overall Incidence | Total | 4/50 (8%) | Mean 8% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, or Keratoacanthoma | | | | | | | | |
| Overall Incidence | Total | 4/50 (8%) | Mean 8% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Trichoepithelioma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
 Vehicle: FEED

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 Report Date: 05/18/2011

| | | Male | | | | Female | | | |
|--------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #Skin: Sebaceous Gland: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| #Spinal Cord: | | | | | | | | | |
| Astrocytoma Benign | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Spinal Cord: | | | | | | | | | |
| Astrocytoma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Spinal Cord: | | | | | | | | | |
| Glioma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Spleen: | | | | | | | | | |
| Fibrosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
 Vehicle: FEED

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 Report Date: 05/18/2011

| | | Male | | | | Female | | | |
|--------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| *Spleen: | | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Spleen: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Spleen: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Spleen: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
 Vehicle: FEED

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| | Male | | | | Female | | | |
|--|-------|------|------|---------|--------|-------|------|------|
| #Stomach, Forestomach: | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | |
| Lipoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | |
| Sarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
 Vehicle: FEED

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| | | Male | | | | Female | | | |
|--|-------|-------|---------|------------|-------|--------|------|------|---------------|
| *Testes: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 41/50 | (82%) | | | | | | |
| Overall Incidence | Total | 41/50 | (82%) | Mean 82% | SD 0% | | | | |
| | | | | | | | | | |
| *Testes: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 | (0%) | | | | | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | | | | |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Thymoma Benign | | | | | | | | | |
| | | 1/48 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/48 | (2.08%) | Mean 2.08% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Thymoma Malignant | | | | | | | | | |
| | | 1/48 | (2%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 1/48 | (2.08%) | Mean 2.08% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Thymoma NOS | | | | | | | | | |
| | | 0/48 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/48 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Thymoma: Benign, Malignant, NOS | | | | | | | | | |
| | | 2/48 | (4%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 2/48 | (4.17%) | Mean 4.17% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
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| | | Male | | | Female | | |
|--|-------|-------------|----------|-------|------------|------------|----------------|
| *Thyroid Gland: C-Cell: Adenoma | | | | | | | |
| | | 12/50 (24%) | | | 6/50 (12%) | | |
| Overall Incidence | Total | 12/50 (24%) | Mean 24% | SD 0% | Total | 6/50 (12%) | Mean 12% SD 0% |
| | | | | | | | |
| *Thyroid Gland: C-Cell: Carcinoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Thyroid Gland: C-Cell: Carcinoma or Adenoma | | | | | | | |
| | | 12/50 (24%) | | | 6/50 (12%) | | |
| Overall Incidence | Total | 12/50 (24%) | Mean 24% | SD 0% | Total | 6/50 (12%) | Mean 12% SD 0% |
| | | | | | | | |
| *Thyroid Gland: Follicular Cell: Adenoma | | | | | | | |
| | | 1/50 (2%) | | | 1/50 (2%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | | | | |
| *Thyroid Gland: Follicular Cell: Carcinoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma | | | | | | | |
| | | 1/50 (2%) | | | 1/50 (2%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
 Vehicle: FEED

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| | | Male | | | Female | | |
|--|-------|------|------|---------|--------|-------|-----------|
| #Tissue NOS: | | | | | | | |
| Paranglioma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #Tongue: | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #Tongue: | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #Tongue: | | | | | | | |
| Squamous Cell Papilloma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #Tooth: | | | | | | | |
| Adamantinoma Malignant | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #Tooth: | | | | | | | |
| Odontoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
 Vehicle: FEED

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| | | Male | | | Female | | |
|---------------------------------|-------|------|------|---------|--------|-----------|-----------|
| *Urinary Bladder: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 1/50 | (2%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Urinary Bladder: | | | | | | | |
| Carcinoma or Papilloma | | | | | | | |
| | | 1/50 | (2%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Urinary Bladder: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Urinary Bladder: | | | | | | | |
| Papilloma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Uterus: | | | | | | | |
| Adenoma | | | | | | | |
| | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | Total | 0/50 (0%) | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Uterus: | | | | | | | |
| Carcinoma | | | | | | | |
| | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | Total | 0/50 (0%) | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
 Vehicle: FEED

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| | Male | | Female | |
|---|-------|------------|----------|-------|
| #Uterus: | | | | |
| Deciduoma Benign | | | | |
| | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | |
| #Uterus: | | | | |
| Leiomyosarcoma | | | | |
| | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | |
| #Uterus: | | | | |
| Polyp Stromal | | | | |
| | | 6/50 (12%) | | |
| Overall Incidence | Total | 6/50 (12%) | Mean 12% | SD 0% |
| | | | | |
| #Uterus: | | | | |
| Sarcoma | | | | |
| | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | |
| #Uterus: | | | | |
| Sarcoma Stromal | | | | |
| | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | |
| #Uterus: | | | | |
| Sarcoma Stromal or Polyp Stromal | | | | |
| | | 6/50 (12%) | | |
| Overall Incidence | Total | 6/50 (12%) | Mean 12% | SD 0% |
| | | | | |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: PERINATAL AND POSTNATAL
 Vehicle: FEED

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| Male | | | | | Female | | | | | |
|-------------------------|--|--|--|--|-----------|-----------|--|---------|--|-------|
| #Uterus: | | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | | |
| | | | | | 1/50 (2%) | | | | | |
| Overall Incidence | | | | | Total | 1/50 (2%) | | Mean 2% | | SD 0% |
| | | | | | | | | | | |
| #Vagina: | | | | | | | | | | |
| Polyp | | | | | | | | | | |
| | | | | | 0/50 (0%) | | | | | |
| Overall Incidence | | | | | Total | 0/50 (0%) | | Mean 0% | | SD 0% |
| | | | | | | | | | | |
| #Vagina: | | | | | | | | | | |
| Sarcoma | | | | | | | | | | |
| | | | | | 0/50 (0%) | | | | | |
| Overall Incidence | | | | | Total | 0/50 (0%) | | Mean 0% | | SD 0% |
| | | | | | | | | | | |
| #Vagina: | | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | | |
| | | | | | 0/50 (0%) | | | | | |
| Overall Incidence | | | | | Total | 0/50 (0%) | | Mean 0% | | SD 0% |
| | | | | | | | | | | |
| #Zymbal's Gland: | | | | | | | | | | |
| Adenoma | | | | | | | | | | |
| | | | | | 0/50 (0%) | | | | | |
| Overall Incidence | | | | | Total | 0/50 (0%) | | Mean 0% | | SD 0% |
| | | | | | | | | | | |
| #Zymbal's Gland: | | | | | | | | | | |
| Carcinoma | | | | | | | | | | |
| | | | | | 0/50 (0%) | | | | | |
| Overall Incidence | | | | | Total | 0/50 (0%) | | Mean 0% | | SD 0% |
| | | | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL
Vehicle: FEED

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Report Date: 05/18/2011

| | Male | | | | Female | | | |
|-----------------------------|-------|-----------|---------|-------|-----------|-----------|---------|-------|
| #Zymbal's Gland: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied